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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|--------------------------|------------------|
| 10/616,959 | 07/11/2003 | Elisabeth Defossa | 38005-0178 | 2135 |
| 5487 | 7590 | 08/11/2005 | EXAMINER | |
| ROSS J. OEHLER AVENTIS PHARMACEUTICALS INC. ROUTE 202-206 MAIL CODE: D303A BRIDGEWATER, NJ 08807 | | | DAVIS, ZINNA NORTHINGTON | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1625 | |
| DATE MAILED: 08/11/2005 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/616,959

Applicant(s)

DEFOSSA ET AL.

Examiner

Zinna Northington Davis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) 5,6 and 8-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 2 is/are rejected.
- 7) ☐ Claim(s) 3, 4 and 7 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

1. Claims 1-12 are pending.
2. Based upon Applicant's Remarks filed May 23, 2005, the improper Markush objection, rejections under 35 U.S.C. 102(b) over Brouwer et al and Aguro-Kanesho Co. LTD, and rejections under 35 U.S.C. 112, 2nd paragraph are withdrawn.
3. Upon further reconsideration, restriction is again required under 35 U.S.C. 121.

The inventions are as follows:

Group I: Claims 1-4 and 7, drawn to a chemical compound, pharmaceutical composition, and a process for preparing wherein the compound of formula I, R8 represents -N.

Group II: Claims 1-4 and 7, drawn to a chemical compound, pharmaceutical composition, and a process for preparing wherein the compound of formula I, R8 represents -O.

Group III: Claims 1-4 and 7, drawn to a chemical compound, pharmaceutical composition, and a process for preparing wherein the compound of formula I, R8 represents -N-C(O)-.

Group IV: Claims 5 and 6, drawn to a pharmaceutical composition using a compound of formula I and at least one other active ingredient.

Group V: Claims 8-12, drawn to various methods of using a chemical compound of formula I.

The inventions are distinct, each from the other because of the following reasons:

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Inventions (I-III) and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed can be used in a materially different process of using that product. See the various methods claimed.

Inventions (I-III) and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed can be used in a materially different process of using that product. At claim 6, see the various active ingredients.

The compounds within the definition of R8 are diverse in scope. A prior art reference which anticipates R8 which represents amino under 35 U.S.C. 102 would not render obvious methoxy under 35 U.S.C 103. Accordingly, the radicals within the definition of R8 are independent and patentable distinct. See Groups I-III.

4. Based upon Applicant's election of November 4, 2004, the species of page 29, Table 1, Example 13, *Group I is the elected invention*. Claims 5, 6 and 8-12 are withdrawn from consideration.

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5. Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1 and 2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Agro-Kanesho Co., LTD (Reference B03, cited by Applicants).

The instantly claimed compounds are disclosed. At page 450, Table 1, see compounds 1-28. The difference between the prior art compounds and the instantly claimed compounds is the substitution of the phenyl ring.

The prior art reference teaches the equivalence of halogen and alkyl when substituted off the phenyl ring. Based upon the teaching of equivalence, it would have been obvious to one of ordinary skill to substitute one radical for another radical such as Cl, Br or methyl. Accordingly, the compounds are deemed obvious modifications therefrom.

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8. Claims 3, 4, and 7 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zinna N. Davis whose telephone number is 571-272-0682.

10. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



**Zinna Northington Davis
Primary Examiner
Art Unit 1625**